REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Rejections Under 35 USC § 102(b)

A. Claims 1, 3, 5 and 6 are rejected as allegedly being anticipated by Raffin *et al.* (United States Patent No. 4,686,100).

B. Claims 1, 3, 6 and 7 are rejected as allegedly being anticipated by Larrick *et al.* (EP0245993)

II. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 112 ¶ 2 as allegedly being indefinite.

I. The Examiner Has Misconstrued The Claims

The Examiner has misunderstood Claim 1's "comprising-consisting of" construction. The transition term "comprising" in Claim 1 modifies ONLY the "therapeutic composition" claim element. The transition term "consisting of" in Claim 1 modifies only the "antibody" claim element. The Examiner, therefore, is incorrect when concluding that the "antibody" element may contain other reactivities. Without waiving this argument, and hereby preserving the right to prosecute the present claims (or similar claims) in the future, Claim 1 has been amended to call out a particular lack of reactivity (discussed below).[1]

II. The Claims Are Not Anticipated

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion, either explicitly or inherently, is not met with either Raffin *et al.* or Larrick *et al.* The Examiner has asserted that the pending claims are anticipated by the doctrine of inherency (*i.e.*, by cited *In re Best*). The

[1] The amendment is fully supported in the specification (see, for example, page 3, lines 20-22).

Applicants disagree and argue that the Examiner has not met the legal standards to show that a antibody raised against full-length C5a shares epitope specificity with antibody raised against a truncated C5a antibody.

The Examiner provides the conclusory statement:

> "Absent evidence that immunization with full-length C5a would not generate antibodies to the truncated form, the antibody preparation obtained by the method of the '100 [or '993] patent would inherently contain antibodies which bind to SEQ ID NO:5 . . ."

Office Action, pg 3 and *pg 4-5.*

These statements are improper because patent law: i) requires the Examiner to prove statements asserting specific recognitions by one skilled in the art[2]; and ii) places the burden on the Examiner to provide extrinsic evidence showing the cited reference teaches more than just a "mere possibility."

First, the Examiner provides the unsubstantiated statement that "It is respectfully submitted that the artisan would recognize that immunization with full-length human C5a would generate antibodies to the truncated form." *Office Action, pg. 3.* The Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

Second, the Examiner has the burden to provide "evidence" from an artisan. Further, the Examiner appears to ignore this requirement:

> [i]n relying upon the theory of inherence, **the examiner must provide** a basis in fact/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

MPEP §2112, *quoting In re Robertson,* 169 F.3d 743 (Fed. Cir. 1999)[underlined emphasis in original, bolded emphasis added]. The Examiner does not provide any evidence that an artisan would consider antibodies to truncated SEQ ID NO:5 to necessarily (*i.e.,* **always**) flow from immunization with a full-length C5a protein.

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[2] To establish the level of skill in the art without reference citations an Examiner must submit an affidavit according to 37 CFR §1.107(b).

Third, the Applicants' specification has facts showing that commercially available anti-human full-length C5a antibodies (*i.e.,* raised to the 74 amino acid sequence; Calbiochem) has "little" if any reactivity "with the N terminal region of human C5a . . ." (See Example 9, page 47, lines 15-16). Based on this evidence, the Examiner must now agree that **it does not necessarily flow** that the specificity of an antibody raised against human full length C5a has antibodies to truncated C5a.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to specify that the composition lacks reactivity to the C-terminus (which is defined on page 11 of the specification). This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants' evidence shows that antibody to full-length C5a does not inherently contain antibody to truncated C5a. On this basis, the Examiner must withdraw the present rejection. Further, the Examiner's anticipation rejection cannot stand because neither Raffin *et al.* or Larrick *et al.* enable the claimed embodiment.

III. Raffin *et al.* And Larrick *et al.* Are Not Enabling

Both Raffin *et al.* and Larrick *et al.* fail to provide any data showing that even a full-length C5a antibody reduces at least one symptom of an existing sepsis infection. The data in Raffin *et al.* is strictly limited to prophylactic administration of full-length C5a antibody:

> In groups II and III, *E. coli* infusion (1 X 10^{10} *E. coli/kg*) was initiated 5 minutes after the initiation of the bolu[s] antibody infusion and continued at a constant rate for 30 minutes using a Harvard infusion pump.

Raffin et al., col 6, ln 14-17. Raffin *et al.,* cannot anticipate the Applicants' claim because the antibody is administered before sepsis occurs (*i.e.* before symptoms), not after.

Data showing effective antibody treatment after sepsis is also lacking in Larrick *et al.* The brief mention of possible treatments are lacking in detail and limited to passive "immunization" and treatment of "at risk" groups. *Larrick et al., pg. 5 ln 1-10.*

Applicants, therefore, respectfully request the Examiner to withdraw the anticipation rejections based upon Raffin *et al.* and Larrick *et al.* and allow the pending claims.

IV. The Claims Are Definite

The Examiner rejects Claims 1, 3 and 5-7 under 35 U.S.C. 112 ¶ 2 as being indefinite because in Claim 1: "There is insufficient antecedent basis for ... ["said symptoms"] ... in the claim. ... there are no symptoms enumerated in the claim and therefore there are no "said" symptoms. It is suggested that Applicant amend the claim to delete the word "said", or recite symptoms of sepsis to be treated." *Office Action pg. 2 ¶ 2.* The Applicants disagree and believe that the Examiner's suggestions are improper.

Claim 1 recites the term "symptoms" in line 3 thus making the recitation of "said symptoms" in line 7 proper. The MPEP provides the following guidance regarding antecedent basis:

> The lack of clarity could arise ... where the claim contains no earlier recitation or limitation ... and where it would be unclear as to what limitation the element was making reference. *MPEP § 2173.05(e).*

The Applicants cannot find either case present in the pending Claim 1. Further, the Examiner requests replacing the term "symptoms" with the actual physiological and or biochemical events occurring in sepsis. This request is contrary to well settled law regarding the claim drafting and interpretation:

> Claims of a patent application '*are to be construed in the light of the specification* and the understanding thereof by those skilled in that art to whom they are addressed'.

Application of Salem, 553 F.2d 676, 683, 193 USPQ 513 (CCPA 1977) (quoting *In re Myers*, 410 F.2d 420, 425 (CCPA 1969) with emphasis added in *Salem*). This original holding has been adopted by the Federal Circuit:

> It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim.

E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988). The Applicants rely on these court guidelines and define the term "symptoms" within the specification, for example:

> The phrase "symptoms of sepsis" ... including but not limited to, increased respiration, increased heart rate, reduced arterial CO_2 saturation, arterial hypotension ... *Applicants' Specification pg 9 ln 8-16.*

Without waiving these arguments, and reserving the right to prosecute the claims (or similar claims) in the future, Claim 1 has been amended in the manner requested by the Examiner. Consequently, the Applicants respectfully request the Examiner withdraw this rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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